UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,623	11/01/2001	Peter J. Oefner	STAN-212	1933

24353 7590 02/25/2004

BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER	
SAKELARIS, SALLY A	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,623	OEFNER ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

8/14.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-51* is/are pending in the application.

4a) Of the above claim(s) *30,31 and 34-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,32,33 and 50-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *42002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Election/Restrictions

Applicant's arguments filed 9/29/03 have been fully considered but they are not persuasive. Applicant's initial election with traverse of Group I, claims 1-9, 12-17, and 27 and the cancellation of nonelected claims 10-11 and 18-26, cancellation of 1-9, 12-17 and 27 and the subsequent addition of new claims 28-51 drawn to the corresponding subject matter of elected Group I is acknowledged. In addition, applicant's response to the notice of non-responsive amendment mailed 1/2/2004, in which they added claims 52-55 and further elected the markers M249(SEQ ID NO:735), M247 (SEQ ID NO:729), and M150(SEQ ID NO:449) of haplogroup II and the corresponding primer pairs(SEQ ID NOS: 735 and 736, 730 and 731, and 450 and 451 respectively) for further prosecution is also acknowledged. Applicant should note that claims 30, 31, and 34-49 are considered to be withdrawn as their recited markers and haplogroups were not elected. Claims 28, 29, 32, 33, and 50-55 are presently being prosecuted to the extant that their methods are limited to the elected markers. Applicant's traversal is on the ground(s) that the claims should not be limited to a particular combination of polymorphic markers, and withdrawal of this aspect of the restriction requirement is respectfully requested. While applicant's arguments are acknowledged, it is maintained however, that the *Official Gazette* and notices posted on the PTO website have included guidance "to include up to 10 nucleotide sequences per application." The examiner retains his/her discretion in the inclusion of "up to 10 sequences." It is further maintained that the examiner adhered to the PTO policy concerning restriction practice as defined in *35 U.S.C. 121*, "if two or more independent and distinct

inventions are claimed in one application, the commissioner may require the application to be restricted to one of the inventions." The examiner maintains that the inventions are distinct, each from the other because of the following reasons:

These sequences including different markers and different polymorphisms are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Thus the claims read on a multitude of groupings of polymorphisms, each of which is separate and distinct one from another because they contain nucleic acid sequences that are structurally separate from one another. The search and examination of all possible groups would pose an enormous burden on the examiner and on the PTO search resources. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their recognized divergent subject matter since all of the polymorphisms would require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore the restriction is deemed proper and is made final.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The present application's claim to benefit of a U.S. provisional Application 60/245,355 filed November 1, 2000, is granted.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code(Pg. 31, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 28-29, 32-33, and 50-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 28-29, 32-33, and 50-55 are indefinite over the recitation of "haplotype Group II" and the markers M249, M247, and M150. These claim limitations make the claims unclear because the specification does not define what is specifically encompassed by haplotype Group II's, markers M249, M247, and M150. The issue is that, the ordinary practioner, when reading this specification to practice the method as claimed, is unable to do so because the disclosure is unclear, vague and indefinite. What are, in a structural sense, markers M249, M247 and M150? Are these 3 markers defining mutations of haplotype Group II? If so, why are they excluded

from Table 2, and furthermore why isn't M60 seen as being exemplary enough to be included with M249, M247, and M150? Furthermore, are these specific markers found consistently in individuals of a specific geographic region? It is not clear what applicant's table 3 is intended to teach. To which haplotype # do each of M249, M247, and M150 correspond and how many people have tested positive for the presence of these markers? Further, what allele is had by each of those people that do carry one of the markers M249(A or G?), M247(T or C?), and M150(C or T?)? There is no fixed definition in the art for what constitutes M249, M247, and M150 or "the plurality of polymorphisms that is representative of allelic forms of at least one haplotype Group II". This last issue is particularly indefinite. If the specification does not identify whether, i.e. M249 in a particular haplotype is an A or a G, it is completely vague and indefinite what has been invented(as well as not described). It is even furthermore vague and indefinite what applicant intends to claim if neither nucleotide given as polymorphic variants are present in their sequence submission of the claimed markers e.g., neither the A or G are present at position 313 of SEQ ID NO: 735(M249)see written description rejection for further explanation. It is therefore unclear, e.g. to what the claim limitations refer. The claims should be amended to clarify to what specific presence/absence of a particular allele that are indicative of the particular ethnic origin of a male.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 28-29, 32-33, and 50-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses the markers of SEQ ID NO:735(M249), SEQ ID NO:729(M247), and SEQ ID NO:449(M150) of haplogroup II and the corresponding primer pairs(SEQ ID NOS: 735 and 736, 730 and 731, and 450 and 451 respectively) with which to amplify these markers. Claims 28-29, 32-33, and 50-55 are directed to encompass sequences that characterize haplotype Group II and the above markers of M249, M247, and M150. A review of the full content of the specification indicates that the detection of the sequences SEQ ID NO:735(M249), SEQ ID NO:729(M247), and SEQ ID NO:449(M150) and each allelic variant, are essential to the operation and function of the claimed invention. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of a "T" at position 224 of SEQ ID NO:729(M247) and the primers with which to amplify the marker sequences (SEQ ID NOS: 735 and 736, 730 and 731, and 450 and 451), the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides that are to be detected in this method as a determinant of a male's ethnic origin, regardless of the complexity or simplicity of the method of isolation. First and most importantly, in a sequence search of the application's own sequences SEQ ID NO:735(M249), SEQ ID

NO:729(M247), and SEQ ID NO:449(M150), major omissions were discovered. SEQ ID NO: 735 was found to lack both an "A" or a "G" at position 313 as proposed by the specification on page 108 to characterize the marker. SEQ ID NO: 449 also lacked both a "C" or a "T" at position 224 as proposed by the specification on page 82. Lastly, SEQ ID NO: 729 lacked the disclosure of a "C" at position 224. If applicant's invention is the method for determining the ethnic origin of a male by analyzing markers with a specific nucleotide present, none of the nucleotides proposed in the specification to be present are disclosed in the specification as filed. Even if arguendo, the sequence disclosure did disclose the nucleotides whose detection is considered by applicant to be the invention, the structure had by these markers is not taught by the specification i.e., M249(A or G?), M247(T or C?), and M150(C or T?). Adequate written description requires more than a mere statement that the sequence is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171,

> 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The issue in this rejection is one of possession and description of the haplotypes where for example, M249(SEQ ID NO: 735) is either an A or G, but mostly that the specification as filed does not disclose the actual structure of either. SEQ ID NO: 449 also lacked both a "C" or a "T" at position 224 as proposed by the specification on page 82. Lastly, SEQ ID NO: 729 lacked the disclosure of a "C" at position 224. No evidence showing which nucleotide is present, but more importantly, even the sheer presence of one or the other nucleotides is present in the claimed haplotype in the specification. As a result, the specification lacks possession of this haplotype. Therefore, none of the structures encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/20/04

JEFFREY FREDMAN
PRIMARY EXAMINER